

The UK Nuclear Industry Good Practice Guide To:

Supply Chain Quality Requirements



This Nuclear Industry Good Practice Guide was produced by the Supply Chain Forum and published on behalf of the Nuclear Industry Safety Directors Forum (SDF)

February 2017

Revision History

Issue Number	Revision Date	Changes
1	February 2017	First Issue

It is recognised that – through the experience of using these Guides – there may be comments, questions and suggestions regarding its contents.

In the first instance, any such comments should be sent to the following

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Foreword

Executive Summary for the contents and subject matter discussed within the Guide

This best practice guide has been established by a technical working-group of the Safety Directors' Forum (SDF) comprising UK Nuclear Licensees (Customers).

The UK Nuclear Industry places Nuclear Safety as the foremost priority. It is committed to working together with its Supply Chain to deliver excellence in everything it does; having the right people, with the right skills in place at the right time. This requires Customers and the Supply Chain to develop a supporting relationship, working together to deliver to the required standards; identifying opportunities to improve performance; preventing concerns escalating and resolving issues promptly.

The UK Nuclear Industry needs to develop capacity within its Supply Chain whilst maintaining a rigorous and clear approach to assuring the quality of products and services. The intention is to assist existing contractors, new entrants and potential new entrants to the UK Nuclear Industry by improving consistency, transparency, and standardisation of the oversight and assurance arrangements, contract quality arrangements, and performance metrics used within the UK Nuclear Industry.

This document is an overarching guide to quality in the UK Nuclear Industry Supply Chain, which is intended to inform existing contractors, new entrants and potential new entrants.

The document comprises three sections providing guidance on:

- Quality oversight and assurance arrangements
- Typical contract quality arrangements
- Quality performance metrics and key performance indicators (KPIs)

The information within this guidance document aligns with the regulatory expectations placed on the UK Nuclear Licensees, and should be shared throughout the nuclear Supply Chain to support quality improvements. This guide supports BS EN ISO 9001 and the existing codes and standards within the Nuclear Industry; Office for Nuclear Regulation's (ONR) Technical Assessment Guides (TAGs); IAEA's General Safety Guides (GSG). These are outlined in Appendix A (Related References).

Safety Directors Forum

In a sector where safety, security and the protection of the environment is, and must always be the number one priority, the Safety Directors' Forum (SDF) plays a crucial role in bringing together senior level nuclear executives to:

- Promote learning;
- Agree strategy on key issues facing the industry;
- Provide a network within the industry (including with government and regulators) and external to the industry;
- Provide an industry input to new developments in the industry; and,
- To ensure that the industry stays on its path of continual improvement.

It also looks to identify key strategic challenges facing the industry in the fields of environment, health, safety, quality, safeguards and security (EHSQ&S) and resolve them, often through working with the UK regulators and DECC (BEIS), both of whom the SDF meets twice yearly. The SDF members represent every part of the fuel cycle from fuel manufacture, through generation to reprocessing and waste treatment, including research, design, new build, decommissioning and care and maintenance. The Forum also has members who represent the Ministry of Defence nuclear operations, as well as “smaller licensees” such as universities and pharmaceutical companies. With over 25 members from every site licence company in the UK, every MoD authorised site and organisations which are planning to become site licensees the SDF represents a vast pool of knowledge and experience, which has made it a key consultee for Government and regulators on new legislation and regulation.

The Forum has a strong focus on improvement across the industry. It has in place a number of subject-specific sub-groups looking in detail at issues such as radiological protection, human performance, learning from experience and the implementation of the new regulatory framework for security (NORMS). Such sub groups have developed a number of Codes of Practice which have been adopted by the industry.

Sub-Group Description

This document is produced by the Supply Chain Forum, which is a sub-group of the Safety Directors' Forum. The Supply Chain Forum was established in November 2014 and brings together a wide range of representatives of nuclear operators, from all the Licensees and Authorisees across the United Kingdom, including:

- Civil, commercial and defence activities;
- Design, operation and decommissioning of nuclear facilities;
- Research facilities.

The purpose of the Supply Chain Forum is to provide guidance that is useful to, and will benefit the widest possible range of UK nuclear operators.

Such guidance is not mandatory, nor does it seek to identify minimum standards. It aims to provide a tool kit of methods and processes that nuclear operators can use if appropriate to their sites and facilities.

These guides are intended to improve the standardisation of approach to the delivery of fit for purpose Supply Chains, while improving quality and reducing the cost of production. They are designed to cater for all stages of a facility's life cycle and for all processes within that life cycle. This includes any interim, continuous and periodic safety reviews, allowing for the safe and efficient operation of nuclear facilities.

When using the information contained within these guides, the role of the Intelligent Customer shall always remain with the individual nuclear operator, which shall retain responsibility for justifying the arguments in their respective Supply Chains. The Office for Nuclear Regulation is a consultative member of the Supply Chain Forum.

The following companies and organisations are participating members of the Supply Chain Forum:



Disclaimer

This UK Nuclear Industry Good Practice Guide has been prepared on behalf of the Safety Directors' Forum. Statements and technical information contained in this Guide are believed to be accurate at the time of writing. However, it may not be accurate, complete, up to date or applicable to the circumstances of any particular case. This Good Practice Guide is not a standard, specification or regulation, nor a Code of Practice and should not be read as such. We shall not be liable for any direct, indirect, special, punitive or consequential damages or loss whether in statute, contract, negligence or otherwise, arising out of or in connection with the use of information within this UK Nuclear Industry Good Practice Guide.

This Good Practice Guide is produced by the Nuclear Industry. It is not prescriptive but offers guidance and in some cases a toolbox of methods and techniques that can be used to demonstrate compliance with regulatory requirements and approaches.

Contents

<i>Revision History</i>	<i>ii</i>
<i>Foreword</i>	<i>iii</i>
Safety Directors Forum	iv
Sub-Group Description	iv
Disclaimer	vi
<i>Contents</i>	<i>vii</i>
<i>Introduction</i>	<i>1</i>
Aims	1
<i>Purpose and Scope</i>	<i>2</i>
Products and Services	2
Terminology	2
Application/Readers Guide	3
<i>Quality Grading</i>	<i>3</i>
<i>Introduction to Subject Matter</i>	<i>5</i>
<i>Oversight of Quality Management System Arrangements</i>	<i>5</i>
SQEP	5
Relevant legislation/regulation	5
<i>Guiding Principles/Concepts</i>	<i>6</i>
Commitment to Working Together	6
<i>Main Body</i>	<i>7</i>
<i>Projects, Products and Services</i>	<i>7</i>
Pre-Contract	7
Contract Placement	7
Design	8
Product and Service Realisation	8
Acceptance and Release	10
Delivery and Receipt	10
<i>Contract Quality Guidance</i>	<i>12</i>
Introduction	12
Contractor Request for Deviation from Contract Quality Arrangements	12
Nuclear Safety Requirements	12
<i>Pre - Contract</i>	<i>14</i>
Quality Management Arrangements	14
Systems and Software – Special Requirements	15
<i>Contract Placement</i>	<i>15</i>

Resource Management	15
Procurement	17
Procurement Information	17
Contractor / Sub-Contractor Selection	18
Review of Contract Requirements	18
Sub-contractor Control	19
<i>Design</i>	20
Control of Design	20
Design Review Requirements	20
Design Output, Review, Checking and Approval	20
<i>Product and Service Realisation</i>	21
Quality Plans	21
Material Certification	22
Product Traceability	23
Verification and Inspection of Products and Services by the Customer	23
Control of Measurement and Test Equipment	23
Deviation and Non-conforming Product or Process	24
Management of Counterfeit, Fraudulent and Suspect Items or Services	24
<i>Acceptance and Release</i>	25
Certificate of Conformance	25
Management Review	25
Release of Goods	25
Release of Goods on Nuclear Sites	25
Records	25
<i>Delivery and Receipt</i>	26
Preservation of Product	26
<i>Appendix A – Related references</i>	27
<i>Appendix B – Typical Oversight & Assurance Activities</i>	28
<i>Appendix C – Glossary</i>	29
<i>Appendix D – Quality Management – Performance metrics</i>	31
<i>General Principles</i>	31
<i>Over-arching metrics</i>	31
Pre-Contract	32
Contract Placement	32
Design (if applicable)	32
Acceptance and Release	33
Delivery and Receipt	33
<i>List of SDF Publications</i>	34

Introduction

UK Nuclear Licensees operate as Intelligent Customers and as such apply the appropriate level of the oversight of quality management system arrangements regarding Nuclear Safety-related Projects, Products and Services.

This best practice guide provides information regarding the levels of oversight and assurance activities that existing Contractors/Sub-contractors and potential new entrants can be expected to adhere to as part of the UK Nuclear Industry Supply Chain. It outlines the expectations of the interactions between the Customer and the Contractor in the context of the oversight of quality assurance activities, a detailed, but not exhaustive list, which can be found in Appendix B.

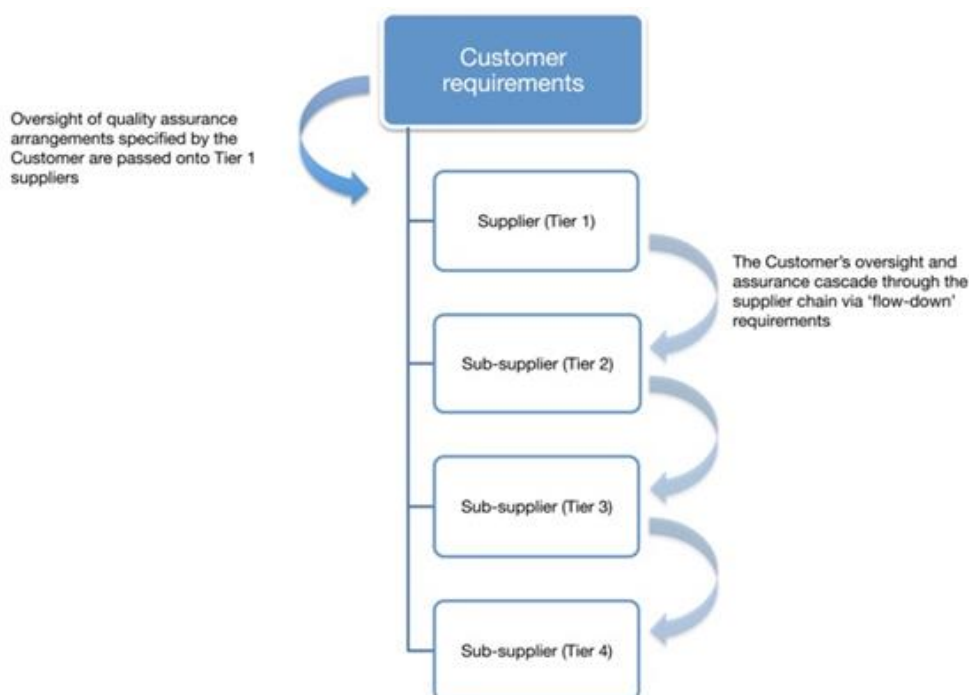
Regulators (such as the ONR) and the Customer reserve the right to undertake oversight of the Contractor's management system arrangements and all work being delivered within the Contract scope including subcontracted work. Oversight may be by means of assessment, inspection, verification, surveillance or formal audit. The Contractor should ensure that its sub-contractors are informed of this requirement.

Aims

This best practice guide aims to ensure the safe, predictable and reliable delivery of Projects, Products and Services through quality control, assurance, verification and validation activities.

It extends to all tiers of the Supply Chain via standard 'flow-down' arrangements, as outlined in the diagram below. Flow-down is the distribution of the Customer's quality arrangements established for the specified Quality Grade. These arrangements should also be adopted regardless of where the Contractors are geographically located and operating.

Flow-down of Customer requirements within the Supply Chain



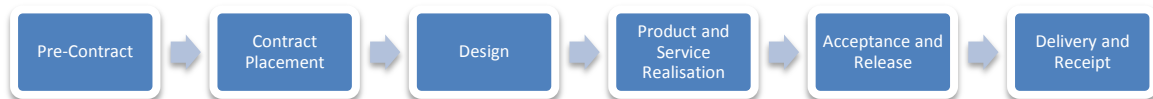
Purpose and Scope

The oversight arrangements, contract quality guidance and performance metrics detailed in this best practice guide reflect principles and activities that promote quality control, assurance, verification and validation of Projects, Products and Services within the nuclear Supply Chain. These oversight and assurance arrangements are designed to minimise the risk of non-conformance, defects and Counterfeit, Fraudulent and Suspect Items (CFSI), whilst ensuring the provenance of materials. This may include, but is not limited to the following:

- identifying and managing risks within the Supply Chain
- principles for establishing levels of contractor oversight.
- principles for the adjustment of oversight to address levels of risk
- qualification of Suitably Qualified and Experienced Persons (SQEP)
- sharing of information across the industry relating to contractor risk

Products and Services

This guide encompasses all phases of Contract delivery by the nuclear Supply Chain as shown below and appendix B: Typical Oversight and Assurance activities



It covers oversight and assurance arrangements for all products and services supplied to UK Nuclear Licensees and as determined by the gradation of risk and safety classification or categorization, including installation and commissioning activities.

Terminology

In this guide the term ‘**Customer**’ is used consistently to describe the organisation at the head of the Supply Chain and usually the UK Nuclear Licensee and Owner of the facility.

In this guide the term ‘**Contractor**’ is used consistently to describe an organisation contracted directly by the Customer to deliver a product or service.

In this guide the term ‘**Sub-contractor**’ is used consistently to describe an organisation either contracted directly by the Contractor (hence tier 2) or contracted at further levels down the Supply Chain (e.g. tier 3, tier 4, tier 5, etc), to deliver a product or service.

Within this guide, where the word “should” appears, UK Nuclear Licensees may utilise the word “shall” within their respective contract quality requirements.

A full glossary of terms used is available at the back of this Guide – Appendix C

Application/Readers Guide

Quality Grading

Nuclear Safety standards and Safety Case management drives a graded approach to the procurement and supply of Projects, Products and Services within the Supply Chain.

This graded approach ensures that the appropriate levels of management system arrangements, including assurance and oversight, are deployed commensurate with the level of risk.

Each Customer will have their own approach to Quality Grading, for example grades typically used are; 01 to 04, A to D, Red to Green etc.

If the product or service being procured can be demonstrated to carry low or no risk, e.g. if failure on delivery or utilisation would have Low to No implications with regard to nuclear/radiological safety; conventional safety; environmental impact or business risk, they may determine to assign a Quality Grade of QG 04. For the purposes of this guide, Quality Grade QG 04 is considered very low risk and is not included.

Typical information associated with the application of Quality Grades is shown below:

Item or Activity		
Status	Quality Grade	Impact
Important For Safety (IFS)	1	Direct impact on Nuclear Safety
	2	Indirect impact on Nuclear Safety
Impact on final product QUALITY		2
	3	Minimal impact on safety but impact on operating performance(s) defined by the technical specification(s) issued by the Customer
OTHERS	4	No impact on the safety nor on the product quality

Source: NSQ-100 GUIDELINES - SECTION C: CLASSIFICATION and GRADING

In accordance with IAEA GS-R-3, the application of management system requirements shall be graded so as to deploy appropriate resources, on the basis of the consideration of:

- The significance and complexity of each product or activity;
- The hazards and the magnitude of the potential impact (risks) associated with the safety, health, environmental, security, quality and economic elements of each product or
- The possible consequences if a product fails or an activity is carried out incorrectly

Quality Grades 01 and 02 (typically very high risk and high risk Projects, Products and Services) should require Customer oversight and assurance activities at the Contractors (and Sub-contractors where applicable) works or locations of the activity. They should require documentation such as Quality Plans; Manufacture Inspection and Test Plans; or method statements to document the quality requirements (See Appendix B).

Surveillance and oversight activities, aligned to the level of perceived risk, should be undertaken by SQEP resources and may be resourced through independent inspection agencies.

Quality Grade for medium risk products and services (e.g. Grades QG 03) should require lower levels of Customer oversight and assurance activities e.g. may be limited to receipt inspection arrangements. Subject to agreement with the Customer, requirements for quality documentation should be reduced, e.g. the provision of a simple Quality Plan and/ Manufacture, Inspection and Test Plan.

For some Customers, an additional Quality Grade code may be applied for the direct supply of product; e.g. in the procurement of proprietary spares and equipment (i.e. typically catalogue / off the shelf / commercial grade quality items) from a source of proven capability. The procurement risk assessment may identify a high risk, however, due to the procurement route, the assurance and oversight activities and requirements for quality documentation may be bespoke to the application.

Where a number of items make up an overall assembly, the risk of failure of each component of the final assembled item must be considered independently and therefore graded accordingly as described in this guide.

Introduction to Subject Matter

Oversight of Quality Management System Arrangements

UK Nuclear Licensees operate as Intelligent Customers and as such apply the appropriate level of the oversight of quality management system arrangements regarding Nuclear Safety-related products and services. This aims to ensure the safe, predictable and reliable delivery of products and services through quality control, assurance, verification and validation activities.

This section provides guidance for quality oversight and assurance arrangements that existing Contractors/Sub-contractors and potential new entrants can be expected to adhere to as part of the UK Nuclear Industry Supply Chain. It outlines the expectations of the interactions between the Customer and the Contractor in the context of the oversight of quality assurance activities, a detailed, but not exhaustive list, which can be found in Appendix B.

Regulators (such as the ONR) and the Customer reserve the right to undertake oversight of the Contractor's management system arrangements and all work being delivered within the Contract scope including subcontracted work. Oversight may be through qualification, inspection, verification, surveillance and formal audit. The Contractor should ensure that its sub-contractors are informed of this requirement.

SQEP

Effective oversight utilises SQEP (Suitably Qualified and Experienced Persons). To be considered SQEP, individuals' professional competence shall be demonstrated and traceable to a competency matrix linked to their role. Professional competence is deemed to be demonstrable knowledge, skills and experience as appropriate to the task or activity being undertaken, and shall be supported by formal training and qualification(s) (national / international).

Relevant legislation/regulation

This document has been generated with consideration of relevant health and safety legislation. Where appropriate legislation has been referenced, but the primary legislation that has influenced this document is:

Office for Nuclear Regulation – Licence Condition Handbook
Office for Nuclear Regulation – Technical Assessment Guide (TAG 077)
International Atomic Energy Agency - Safety Standards

Guiding Principles/Concepts

The following principles underpin the successful application of oversight of Quality Management system arrangements within the UK Nuclear Industry Supply Chain, and Customers and Contractors shall act in accordance with these principles at all times:

- UK Nuclear Licensees will act as Intelligent Customers
- Contractors shall satisfy customer requirements at all times
- Contractors shall support Nuclear Safety requirements at all times
- Contractors shall understand and apply the principles of configuration management
- Contractors shall understand and operate robust change control processes
- Contractors shall promote cultures and behaviours that support the principles of the nuclear industry
- UK Nuclear Licensees (current and future) and the Supply Chain will be transparent and share information, including lessons learnt from Operational Experience (OE) and discovery of CFSI

Commitment to Working Together

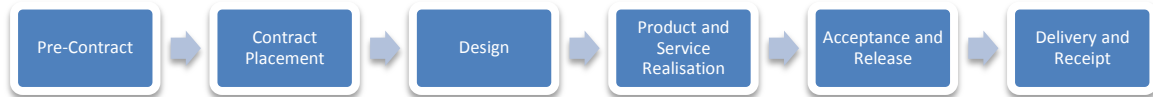
The UK Nuclear Industry is committed to working together with its Supply Chain delivering excellence in everything it does; having the right people, with the right skills in place at the right time. This requires Customers and the Supply Chain to develop a supporting relationship, working together to deliver to the required standards, identifying opportunities to improve performance, preventing concerns escalating and resolving issues promptly through:

- open and honest communication
 - At all levels and tiers, throughout the Supply Chain – raising queries and concerns as they become known
 - Checking for understanding and compliance at all levels and tiers of the Supply Chain – ensuring that specifications, requirements, and identified processes are flowed down, understood, and met
- sharing learning
 - Identifying and building on best practice
 - Utilising Learning from Experience (LfE) to prevent issues and improve performance
- continuous improvement
 - Having the right measures,
 - Using the right tools,
 - Looking at the right things
- structured problem solving
 - Basing decisions on data
 - Addressing the root cause
 - Implementing robust corrective actions

Main Body

Projects, Products and Services

This guide encompasses all phases of Contract delivery by the nuclear Supply Chain as shown below and Appendix B: Typical Oversight and Assurance activities



It covers oversight and assurance arrangements for all products and services supplied to UK Nuclear Licensees and as determined by the gradation of risk and safety classification or categorization, including installation and commissioning activities.

Pre-Contract

During the Pre-Contract phase and prior to contract award, Customers should ensure that prospective contractors (all tiers) fully understand that products or services being procured are a principal means of ensuring Nuclear Safety. An assessment in the form of a pre-qualification questionnaire (PQQ) or Invitation to tender (ITT) may take place to verify the Contractor's capabilities. Looking at, for example: management system(s), processes and resources (as applicable to the Customer specification and in line with the relevant codes and standards), including the Contractor's culture in relation to Nuclear Safety.

Additionally, the Contractor's ability to meet the Customer/contract requirements (including design requirements), Technical Specification, Quality Grading, materials selection and processing may be assessed. Further Assessments may take place to establish the resources and capabilities of sub-contractors. Initial Pre-Contract meetings may also take place to understand oversight and assurance arrangements. All of the above Pre-Contract steps and criteria will aid in the evaluation and selection of contractors, commensurate with the risk related to the Project, Product or Service.

Some UK Nuclear Licensees shall use the above to form the basis of a formal supplier approval.

Contract Placement

Throughout the Supply Chain, the oversight of quality assurance arrangements may include opening meetings between the Customer and Contractor to ensure the understanding of Customer works information, specification and requirements. Pertinent requirements will be cascaded to the sub-contractors within the Supply Chain as applicable.

Initial meetings may include a review of all relevant quality certifications/accreditations, and the submission to the Customer for approval or acceptance of Quality Plans, Manufacture, Inspection and Test Plans (MITP) and Supply Chain Maps.

Discussions on the method of manufacture and constructability may also take place between the Customer and Contractor where appropriate. Where specified, and prior to being carried out by the Contractor, special processes and testing procedures that require qualification shall be documented as a written procedure and submitted to the Customer for approval/acceptance.

The Contractor should develop and implement a risk based assurance programme which aligns to the graded approach to procurement. The Contractor should also document and establish Sub-Contractor assurance and oversight arrangements to ensure compliance with the Customer specifications, standards and contract quality requirements. These arrangements should be tailored to mitigate risk to Nuclear Safety.

Design

Where contracts cover design services, oversight of quality assurance arrangements may incorporate a gated or phased/staged review of documentation and design inputs/outputs by the Customer. These arrangements also require the Contractor to understand and acknowledge the Customer requirements and design inputs/outputs. Customers seek to demonstrate assurance through the oversight, review and participation in the Contractor's design and development control processes, which may include verification and validation of:

- design requirements and inputs/outputs
- Design Manufacture, Inspection and Test Plans (including hold/witness points)
- design control
- design change
- design reviews
- SQEP resources review
- Supply Chain Maps

Product and Service Realisation

The fundamental elements of oversight of quality management system arrangements may be established through a quality contract review meeting undertaken between the Customer and the Contractor. This aims to ensure that quality requirements are understood and have been cascaded to all Supply Chain tiers. These activities may be conducted by a number of different parties, notably the Customer, Contractor (all tiers), and / or independent third party inspectors.

Roles nominated to perform oversight activities may include: Quality Engineer; Manufacturing Engineer; Field Engineer; Auditor / Assessor or Quality Control and Assurance personnel amongst others; some of which may be third parties employed by the Contractor. These SQEP resources should be matched to the requirements of the contract and have clearly defined roles, responsibilities and competencies. A designated individual may be nominated by the Customer to act as a single point of contact on issues of oversight and assurance.

During the Product and Service Realisation phase, Customers and Contractors are expected to partake in oversight of quality assurance activities throughout the Supply Chain to ensure compliance to the management arrangements and approved/accepted documentation, including:

- Quality Plans
- Manufacture, Inspection and Test Plans (MITPs)
- Design and Development Plans
- Software Plans

Oversight requires the physical attendance at the hold-points / witness points identified on MITPs (including a review of Lifetime Records) by the Customer / nominated inspection authority who should sign, date and stamp all completed quality documentation (such as MITPs) as a record of acceptance. For witnessing of hold-points / witness points it is the Contractor's responsibility to contact the Customer and/or third party personnel in line with agreed timescales and may require a level of detailed planning. Where specified within the Customer requirements / specification, Contractors will be expected to perform testing to approved / accepted procedures, with the results of any tests appropriately recorded. The testing arrangements shall be managed through the MITPs and it is the Contractor's responsibility to contact the witnessing authority to attend in person when required.

The Customer should be afforded, with reasonable notice, unrestricted access to the Contractor's or Subcontractor's facilities to carry out oversight. Upon request, the Contractor should also report progress against their Assurance / Audit / Assessment programme to the Customer.

During the Product and Service Realisation phase, Contractor performance will be periodically monitored and assured throughout all tiers of the Supply Chain, and recorded via inspection / verification / audit / Assessment reports (including dimensional inspection) amongst others. The results of these oversight activities will be subject to analysis and intervention taken when necessary. The objective evidence associated with oversight and assurance activities shall form the basis of the Lifetime Records (LTRs), and Contractors can expect this to be reviewed at any stage during the contract.

The agreement of the Customer must be sought prior to introduction of any variation or deviation from the Customer specified requirements that occurs during the lifecycle of the product or service, or for any query of a technical nature. The Contractor should also report to the Customer deficiencies identified from their oversight and assurance activities that will affect compliance with contractual requirements. Corrective actions should identify remedial measures and preventive actions to avoid recurrence. Any variation or deviation should be managed by a Change Control process, recorded by the Contractor or Sub-Contractor, approved by the Customer and closed out prior to inclusion in the LTR. These changes will be assessed by the Customer to determine whether there is an impact upon Nuclear Safety.

Contractors are responsible for ensuring that hold points / witness points, agreed within the Manufacture, Inspection and test Plan, at the opening up meeting, are adhered to; that variations and or deviations from Customer requirements are authorised and records maintained. The Customer will then provide oversight activities against the above. If during oversight activities, the above cannot be demonstrated the following courses of action may apply:

- rejection of products or services
- intervention by the Customer or third party personnel
- corrective action and Root Cause Analysis
- a halt to manufacturing, supply or service activities when supported by evidence
- intervention by a regulatory authority (such as the ONR, EA, or HSE).
- increased surveillance activities

When necessary, advice and input from the Customer or third party manufacturing specialists may be provided to resolve manufacturing or delivery problems. The Supply Chain can expect an ongoing assessment of their resources, personnel, systems and processes, the frequency of which may vary dependent upon the risk profile and safety significance of the products or services. Where appropriate, specific oversight activities will be performed on the Contractor's quality assurance arrangements such as identification and traceability; materials segregation; cross-contamination; CFSI, preservation; controlled use of non-metallic materials; and receipt inspection etc. These arrangements should be cascaded to all sub-contractors as applicable and where required by the contract.

Acceptance and Release

Where applicable, the Customer or independent third party organisation will perform verification or assessment related to the acceptance of products or services prior to the interim or final release. This may include the review of Lifetime Records and acceptance criteria at the Contractor's premises. Certificates of Release may be required to confirm acceptance and authorisation to dispatch. In addition, when required by the MITP this Customer oversight may apply at any sub-contractor within the Supply Chain.

Delivery and Receipt

Contractor arrangements for the transport, receipt and storage of products or sub-assembly products shall be verified through a receipt inspection process. Receipt inspection forms part of the oversight and assurance activities and is to be applied throughout the Supply Chain. These arrangements should be sufficient to maintain product traceability and prevent damage, loss, deterioration, and also detection and inadvertent use of CFSI.

On completion of the contract, various aspects of Contractor performance may be assessed and analysed, the results of which will be used to:

- influence current/future oversight and quality assurance arrangements
- influence the placement of future contracts
- drive continuous improvement within the Supply Chain
- to share lessons learnt and best practice

Contract Quality Guidance

Introduction

Nuclear quality standards aim to support the delivery of excellence in all aspects of services, operating safely, securely, reliably and predictably. To achieve this aim, it is a requirement for the Supply Chain to deliver the quality of products and services safely, to schedule, to the specified requirements and to the agreed cost.

The purpose of this section is to outline a typical set of contract quality requirements that will enable the delivery of products and services to the UK Nuclear Licensee's associated quality grades (typically very high risk, high risk, medium risk and low/minimal risk). These arrangements take the form of activities, processes and procedures that encompass, amongst others: Quality Management arrangements, resource management, sub-contractor control and the maintenance of records. This guide emphasises those elements above the latest edition of BS EN ISO 9001 that are key to successful delivery of products and services to the UK Nuclear Licensee's Supply Chain requirements.

Contractor Request for Deviation from Contract Quality Arrangements

If the Contractor is unable to comply with any of the requirements defined within the Customer-specific contract quality requirements, the Contractor should apply to the Customer to request agreement that it is acceptable to deviate from the contracted requirements. These records should be retained within the Lifetime Records.

Nuclear Safety Requirements

According to IAEA SF-1, 'Nuclear Safety' means the protection of people and the environment against radiation risks and the safety of facilities and activities that give rise to the radiation risks.

In order to achieve this aim, the UK nuclear licensees need their Supply Chains to deliver goods and services to the agreed specifications, works information, codes and recognized standards. A key focus is ensuring that all Supply Chain personnel involved in design, manufacturing, fabrication, construction, inspection and testing understand how their role impacts upon Nuclear Safety and how the failure of a product or service can impact upon the associated plant and local community.

The design phase needs to concentrate on the four criteria of Criticality (control conditions to prevent a criticality), Control (prevent chemical reactions that could challenge containment), Containment (keep nuclear inventory where it should be) and Cooling (stop nuclear material overheating). Design is the first layer of defense. It is at the design stage where the most impact on Nuclear Safety can be made; therefore it is vital that any party undertaking design understand the impact of a failure.

The requirements of the design then need to be transmitted into the construction (The process of manufacturing and assembling the components of a facility; the carrying out of civil works; the installation of components and equipment; and the performance of associated tests) phase such that the design intent can be realised via the quality of

workmanship, materials, methods, systems and competence. This will involve ensuring the manufacturing, fabrication and construction trades understand how the quality of their workmanship can impact on Nuclear Safety e.g. poor installation of pipe-work may lead to loss of containment of nuclear materials. Other requirements include construction personnel understanding the constraints and associated risks of a construction / manufacturing site being next to Nuclear Buildings therefore there may be restrictions on the use of cranes or vibrating machinery that could affect sensitive instruments.

There are 8 internationally accepted principles of a strong Nuclear Safety Culture:

- everyone is personally responsible for nuclear safety.
- leaders demonstrate commitment to safety.
- trust permeates the organisation.
- decision-making reflects safety first.
- nuclear technology is recognised as special and unique.
- a questioning attitude is cultivated.
- organisational learning is embraced.
- nuclear safety undergoes constant examination

For reference, the Institute of Nuclear Power Operators (INPO) have defined ten essential traits and associated attributes of a healthy nuclear safety culture, with the goal of creating a framework for open discussion and continuing evolution of safety culture throughout the nuclear industry. These traits include:-

- the Contractor should establish and promote an effective Nuclear Safety culture aligned to the traits and attributes defined above within its own organisation and that of its Supply Chain by:
 - ensuring a common understanding of the key aspects of Nuclear Safety within the organisation
 - providing the means by which the contractor is able to develop a Nuclear Safety culture
 - reinforcement of a learning and questioning attitude at all levels of the organisation about Nuclear Safety
 - the Contractor should ensure that all personnel involved in the provision of work for the Nuclear Licensee/Customer understand any Nuclear Safety implications of failure of the product or service to meet the specified design intent
 - the Contractor should ensure that the ten traits of a Nuclear Safety culture are promoted throughout the organisation so that all personnel are aware of them and understand them
 - the Contractor should ensure that Personnel are aware of the implications of CFSI being deployed in the Nuclear Supply Chain site
 - finally, the transition from manufacturing; fabrication; construction; through commissioning to operations needs to be appropriately managed in order to ensure the necessary knowledge is passed over to the requisite personnel.

Pre - Contract

Quality Management Arrangements

All Contractors should maintain a quality management system that is appropriate to the quality grade defined. Where certification to a standard e.g. BS EN ISO 9001 is required this should be certified by a United Kingdom Accreditation Service (UKAS), accredited Certification body or internationally accepted equivalent, as defined by the International Accreditation Forum (IAF).

At contract award the Contractor should demonstrate their capability to deliver products and services in accordance with the Customer's requirements.

In the event that the Contractor's quality management system is made up of a multiple number of certified quality management systems (alliance/ collaborative partnerships), the Contractors' - should make their operational quality management system arrangements and the Alliance / partnership Quality Plan available to the Customer within the agreed timeframes.

The Contractor should appoint a SQEP Quality Management representative, supported by competent experienced personnel, to ensure effective implementation of the quality management system arrangements.

Where proposed changes to the Contractors' quality management system could have the potential to impact upon product quality or affect (lead to the loss of) the Contractors' certification, those changes should be submitted, by the Contractor, to the Customer for acceptance / approval.

When responding to any Contractor request for the Customer acceptance / approval of changes to the Contractor's quality management systems, the Customer should respond in writing; and provide any reasons for determination that the Contractor's proposed changes to its quality management systems are unsuitable.

The Contractor should provide evidence of compliance to the Customer specific contract quality requirements to the Customer upon request

The Contractor's management arrangements should address all statutory and regulatory requirements appropriate to the Contract scope. The Contractor should identify and have access to these requirements, determine how they apply, and implement them when providing product(s) or service(s).

The Contractor should ensure that all personnel executing the contracted scope of work are aware of and understand the management system arrangements and any amendments relevant to the scope of work.

The Contractor should ensure that documentation requiring submittal to the customer for information or for review and acceptance should be submitted as detailed in the Customer specific contract quality requirements.

The Contractor's procedure for controlling documents between Sub-contractors and the Customer should ensure documents are clearly identifiable to each sub-contractor. Version control of documents between the Contractor, Sub-contractor and the Customer should be appropriately managed.

The Contractor should have a business continuity process in place that identifies potential threats to the organisation and the impacts to business operations those threats, if realised, might cause. The Contractor should have in place an effective response that safeguards the interests of its key stakeholders, reputation, brand and value-creating activities.

The Contractor should have a documented process for Learning from Experience to demonstrate improvement, and be able to show effective implementation

Contractors engaged on nuclear projects may be subject to further or additional Customer specified Quality Standards.

Systems and Software – Special Requirements

As a minimum, where the Contract includes design, development, supply and installation, modification or maintenance of software, including Programmable Electronic Systems (PES), then the current revisions of ‘BS ISO/IEC 90003 Software Engineering Guidelines for the Application of BS EN ISO 9001:2008/2015 to Computer Software’ is applicable together with BS ISO/ IEC 12207 Systems and Software Engineering – Software Life Cycle Processes.

Where the Contract includes work on a PES that forms all or part of a safety system, the Contractor should demonstrate that they operate functional safety management arrangements that align with the principles set out in the latest revision of BS EN 61508 (all appropriate parts) – “Functional Safety of Electrical / Electronic / Programmable Electronic Safety Related Systems”.

Contract Placement

Resource Management

The Contractor should implement an induction course. The Contractor should ensure that all personnel deployed on the works receive the induction course prior to commencing work on the contract. The induction course should as a minimum include:

- Nuclear Safety
- safety requirements
- security requirements
- overview of the works
- mandatory procedures
- standards and specifications requirements briefs

The Contractor should determine and provide the appropriate number of SQEP resources required to deliver the contracted scope of work and agree the levels with the Customer.

The Contractor should ensure that all personnel they assign to undertaking work for the Customer are SQEP to deliver the assigned work. There should be a clear auditable trail that demonstrates that the Contractor's staff is equally as SQEP as licensee staff would be for the same role.

The Contractor should implement and maintain a competency/training register supported by appropriate training and qualification records. The register should identify:

- all personnel engaged on the works
- role specification
- status of training received for each individual
- experience of each individual
- assessment of competence of individual against their role specification
- forward Plan to close out identified competency requirements

The Contractor should routinely perform documented reviews of personnel to maintain competency and succession planning

The Contractor should notify the Customer of any deficiencies identified with personnel competency that may affect the product or service provided. The Contractor should take corrective actions to eliminate personnel competency deficiencies

The Contractor should, upon request, provide documented evidence of personnel competency to the Customer who reserves the right to interview personnel controlling quality related activities

The Contractor should define and implement appropriate arrangements to control any change to its organisational structure or resources which may affect environmental, health and safety, security and quality performance

The Contractor should notify the Customer formally of any organisational changes that could impact on environmental, health and safety, security and quality performance

The Contractor should be able to demonstrate the qualification and independence of personnel verifying or inspecting work from those performing the work

All inspection and test quality control (special processes – welding, NDE, heat treatment etc.) personnel deployed on the works are SQEP

All testing and inspection practitioners should be experienced in the application of the technique to the specific material.

Procurement

To mitigate the risk of failure, the Contractor should implement a graded approach in accordance with this guide for the procurement of Projects, Products and Services.

Procurement Information

The Contractor should ensure that the procurement information accurately specifies the Project, Product or Service to be purchased.

The Contractor should ensure that the requirements of the contract, the appropriate standards, and necessary requirements to deliver the Projects, Products and Services specified, are flowed-down to, and understood by, all tiers of the Contractor's Supply Chain.

The Contractor should ensure the purchasing information accurately specifies the requirements for acceptance of Projects, Products and Services, to include as applicable:

- reference to the customer's contract requirements
- Quality Grade
- specification(s) and works information
- drawing(s)
- material Type
- quantity
- certification requirements
- inspection requirements, at vendor, on delivery or both
- functional testing requirements, at vendor, on delivery or both
- any special requirements such as packing, extra testing etc
- requirements for procured services

If required, the Contractor should provide copies of unpriced purchase information to the Customer upon request.

If required, and where agreed at the Contract opening up meeting, copies of purchase information raised by the Contractor which is equivalent to Quality Grade 01/02 should be sent to the Customer.

Contractor / Sub-Contractor Selection

The Contractor should have a process for sub-contractor selection through assessment and analysis of amongst other things their competencies, facilities and equipment to ensure that they have the capability to conform to the contract requirements, delivering Projects, Products and Service safely, to schedule, of the correct quality and to cost.

Instruction from the Customer to use a specific sub-contractor does not absolve the Contractor from completing an evaluation of the sub-contractor's capabilities to meet the requirements and commitments of the contract.

The Contractor should assess the sub-contractor's capability to plan and meet the required capacities beyond existing or new contracts.

The Customer may review, with the Contractor, the evaluation of sub-contractors and partake in the granting of formal approval / acceptance.

The Contractor should ensure that any weaknesses / risks identified during the evaluation / assessment process are managed post contract award.

Review of Contract Requirements

The Contractor should ensure, by demonstration, that all contract requirements for the scope of work have been reviewed, agreed and understood prior to the commencement of work both within their own organisation and their Supply Chain.

Where applicable, the Contractor should, via opening up / initial meetings held with their sub-contractors, confirm the understanding of the Customer works information pack / Purchase Orders and explain each clause of the specification to ensure full understanding of the requirements.

The following elements, where included within the contract, should be reviewed:-

- Quality (including Nuclear Safety and specification awareness briefs)
- project/contract management
- commercial
- health and safety
- project controls (planning, programme and costs)
- risk
- engineering
- construction
- commissioning
- operations and maintenance
- provision of product samples (when requested)
- Lifetime Records (LTRs)

The Contractor should establish a process for ongoing contract review throughout the life of the contract.

Records of the ongoing reviews and the conclusion reached should be retained and form part of the lifetime record.

Sub-contractor Control

The Contractor should ensure that the full extent of their Supply Chain has a clear understanding of all Contract technical and quality specified requirements, and that understanding is tested.

If the Contractor sub-contracts work, the Contractor is responsible for controlling the scope of work in accordance with the associated Quality Grade and the specified requirements

The Contractor should implement a process for ongoing verification and monitoring of their sub-contractors to ensure that they are delivering products and services safely, to schedule, to the specified requirements and to the agreed cost.

Contractors / sub-contractors should produce a diagram that shows the totality (inclusive of materials, components, sub-assemblies, assemblies and plant items) of the Supply Chain delivering the contracted scope of work. The diagram may take the form of an organisational chart or equivalent, which may be phased to meet contract deliverables. The diagram should specifically include:

- Organisational hierarchy between contracting parties
- Names of contracting parties
- Quality assurance arrangements (audit, surveillance, inspection and testing) that should be applied to each sub-contractor.
- The Contractor should submit the diagram to the Customer with the tender for acceptance.
- The diagram should be maintained throughout the lifetime of the contract.

When specified, Contractors supplying products or services directly to the Customer should, in accordance with the Contract, provide for acceptance of a Supply Chain Map or a schedule of intended sub-contractors.

The Contractor should provide to the Customer details and justifications of any proposed increase or reduction in the control over its sub-contractors or replacement of any sub-contractors.

Design

Control of Design

The Contractor should ensure that all design interfaces are clearly defined and controlled.

The Contractor should ensure that roles and responsibilities of appropriate design disciplines, for example, mechanical, electrical, process, safety and civil, are clearly understood and communicated to ensure their involvement at the appropriate stages.

The Contractor should ensure that all design documents and design changes issued to the Customer are controlled by the documented management system process. Design changes should be conducted at the same level as the original design review and verified accordingly.

The Contractor should ensure that IT software used in analysis and computation of high risk activities is acceptance tested, is validated, has a test plan, and is not used beyond its life cycle without appropriate validation.

Design Review Requirements

When the design responsibility lies with the Contractor as defined within the contract, the Contractor should identify and implement their proposed design reviews on a Quality Plan that has to be accepted by the Customer prior to the commencement of work.

Third party design verification activities should be documented and included within a Quality Plan to ensure that responsibilities and communication interfaces are clearly defined.

The Contractor should submit all documents to be considered at design review to the Customer at an agreed period in a fully approved state prior to the design review

The Customer reserves the right to participate in Contractor design reviews.

The Customer reserves the right to identify any design activity which requires confirmation or third party verification.

The Contractor should document the results of all design reviews and transmit the results to the Customer. Actions resulting from design reviews should be completed before final Customer approval of the design.

Verification reviews of design calculations and analysis performed by alternative means should be controlled to determine when, by what method, and by whom the calculations were performed, and be traceable back to the original design.

Design Output, Review, Checking and Approval

Review, checking and approval of design outputs should be undertaken by SQEP resources independent of those having direct responsibility for the work being performed.

Design output, whether in electronic or paper form, should be considered as Lifetime Records and delivered in accordance with the Records section of this guide.

Product and Service Realisation

Quality Plans

The Contractor should submit the Quality Plan(s) and Manufacture, Inspection and Test Plans to the Customer for acceptance within the timeframe agreed with the Customer.

The Contractor should not commence work identified in the Quality Plan and Manufacture, Inspection and Test Plans prior to confirmation of acceptance by the Customer

Where a Manufacture, Inspection and Test Plans or method statement is required by the Technical Specification and the Quality Grade, the Contractor will agree the content with the Customer at the Opening up / Initial Meeting.

The distribution for review and approval of Quality Plans and/or Manufacture, Inspection and Test Plans should be agreed at the opening up / initial meeting for the Contract, Project, task specific purchase orders or operations.

The Contractor should ensure a Quality Plan and/or Manufacture, Inspection and Test Plans is/are in place for the contracted scope of work. Where the work covers a number of phases for example design, manufacture, construction, installation and commissioning, separate quality plans should be prepared and submitted in accordance with the Supply Chain model / Sub-Contractor Map.

The Contractor should document in quality plans the controls to be applied to its subcontractors. Any change to an approved/accepted quality or Manufacture, Inspection and Test Plans plan should be resubmitted to the Customer for approval and/or acceptance.

Specialist processes within the specification should be identified within the Quality Plan and Manufacture, Inspection and Test Plans. These will require approval by the Customer. Typical special processes include but are not limited to welding, pipe work bending, heat treatment, non-destructive testing, material finishes and concrete mix design.

For products and services, the Quality Plans and /or Manufacture, Inspection and Test Plans should conform to the following criteria:

- the Manufacture, Inspection and Test Plans should be prepared listing the activities necessary to demonstrate compliance with the specified requirements and to discharge the work. The activities should be listed in a logical sequence and be broken down into a level of detail required to discharge the work, for example, phases associated with the contract lifecycle and different packages of work;
- the Manufacture, Inspection and/or Test Plans should identify against activities all applicable procedures, controlling arrangements, accountability for delivery and associated records. The wording and output of the activity should be clear, concise and unambiguous;
- the Manufacture, Inspection and/or Test Plans should identify the minimum records to be included in the Lifetime Records. These records should be

reviewed, approved and accepted in accordance with the specification and contract requirements;

- the Customer reserves the right to identify hold points in the Manufacture, Inspection and Test Plans. The Customer representative may identify hold points in the MITP beyond which work must not proceed without the Customer's verification and/or permission. If work commences prior to the Customer acceptance of the Quality Plan, or work progresses past a hold point without the required sign off on the Quality Plan, the Customer should raise a non-conformance requiring corrective and preventive action;
- to monitor the work, and Manufacture, Inspection and Test Plans should facilitate the signing off of all activities against the agreed Inspection Activities identified in the approved Quality Plan. Manufacture, Inspection and Test Plans should be kept up to date to reflect current status that is, signatures / dates recorded.
- the Manufacture, Inspection and Test Plans should consist of three main parts: cover sheet, documentation sheet and activity sheet. The cover sheet should typically identify the following:
 - company name
 - Title
 - reference numbers (Contract number, contractor reference number and sub-contractor reference number if applicable)
 - plant item number or material master number
 - scope of work the Quality Plan covers
 - activity codes and description
 - SQEP nominated roles for signing off the Quality plan activities
 - Quality Plan acceptance – (names, signatures and dates)
 - final sign off when the Quality Plan is complete
- the documentation sheet should identify all standards and specifications applicable to the scope of work;
- the activity sheets should identify activities and activity codes, documents, nominated roles and records required to be generated to be included in the lifetime records;
- when completed the Manufacture, Inspection and Test Plans should be able to act as a route Map from the original scope of work, to the underpinning Lifetime Records.

Material Certification

The Contractor should supply to the Customer original material certificates in accordance with BS EN 10204, listing the mechanical and chemical properties as required by the contract specification. Where this is not possible copies should be taken and endorsed by authorised personnel as verified true certified copies of the original.

Where a product has been manufactured from a previously certified material the Contractor should provide endorsed certificates of both material products produced by one manufacturer and reworked by another manufacturer, for example fittings made from pipe or plate, flanges made from a forging or plate.

The Contractor should review and endorse the Original Material Certificates or certified copies to verify conformance with the contract specification prior to the commencement of work.

Stockist certificates are not acceptable when original material certificates or certified copies are specified within the contract specification.

The Contractor's authorised personnel reviewing original material certificates for conformity should be SQEP to perform such reviews.

Product Traceability

The Contractor should have a documented process for identification and traceability of materials and products during storage, manufacturing and delivery in accordance with relevant specified requirements.

The Contractor should, where required, ensure stockists maintain a system that provides item traceability in accordance with the relevant specified requirements.

Verification and Inspection of Products and Services by the Customer

Acceptance of any aspect of a product or service by the Customer does not absolve the Contractor of his responsibility to ensure conformity to product and service requirements.

The Contractor should provide the Customer with the agreed notice period of a Quality Plan hold point requiring the Customer attendance

To request verification of inspection and test by the Customer nominated inspectorate, the Contractor should notify as a minimum the Customer within the timeframe specified by the Customer.

The Contractor should establish a process for goods inward inspection. The process should ensure the following:

- plant and materials are received with a copy of the relevant (final certificate of inspection etc.) or equivalent certificate
- plant and materials should be accompanied by a manufacturer's delivery note and should be checked for quantities and transport damage.
- plant, materials and associated certification are booked into an approved storage or lay down area and allocated with a unique identification number.
- plant and materials that are found to be damaged or considered to be outside of specified requirements are immediately quarantined.
- identification of CFSI

Control of Measurement and Test Equipment

The Contractor should maintain a register of measurement and test equipment.

The Contractor should maintain measurement and test equipment, calibrated and traceable to International or national standards for the duration of the contract

The Contractor should notify the customer of any product that may be affected by the failure of measurement and test equipment or by the measurement and test equipment failing recalibration. The Contractor should evaluate the impact on product affected by

such equipment; this product should be treated as non-conforming product until demonstrated otherwise

Deviation and Non-conforming Product or Process

The Contractor should establish a documented process to identify, record, clarify and resolve technical problems with respect to the Customer and/or Customer requirements prior to or during the implementation of the contracted work scope.

The Contractor should establish a documented process to identify, clarify, resolve and close out non-conformances, in a timely manner, throughout the life of the contract.

The Contractor should establish a documented process to identify a request for deviations or a justification for the use of Non-Conforming product from the Customer specified requirements

Upon identification of nonconforming product or service the Contractor should ensure the product is clearly identified, segregated, controlled, recorded, and reported to the appropriate level of management within the organisation and then reported onwards to their Customer.

The Contractor should establish a process to review the cumulative effect of non-conformances, Technical Queries and Concessions raised. The output of these reviews should be submitted to the Customer design authority.

The Contractor and its sub-contractors should not repair work or correct spoilt work after (final) inspection by the nominated inspectorate without the prior written approval from the Customer.

At any time prior to or post-delivery of the product, the Customer reserves the right to raise a non-conformance and undertake Root Cause Analysis or similar.

Management of Counterfeit, Fraudulent and Suspect Items or Services

The Contractor should ensure that processes are in place to mitigate the risk of CFSI being deployed to a UK Nuclear Licensee. The processes should include identification of CFSI, assurance of product source, selection of Sub-Contractors and other suppliers and verification that purchased products meet the specified requirements.

In the event of CFSI being found the Contractor should immediately quarantine the item, notify the Customer in case a similar item is in use, and initiate the non-conformity process as described in Deviation, Non-conforming product or process

The Contractor should ensure that processes are in place to control and document the disposition of items identified as Suspect. The Customer should be provided records of the dispositions of Suspect Items, as agreed at the opening up meeting.

In the pursuance of Nuclear Safety, all such CFSI events should be communicated to the Customer

Confirmed CFSI should not be allowed to re-enter the Supply Chain, but the information should be treated as Learning from Experience and disseminated to all UK Licensees

Acceptance and Release

Certificate of Conformance

Where required, the Contractor should supply a [document certified](#) by a [competent authority](#) that the supplied good or [service](#) meets the [required specifications](#). This is also referred to as a [certificate of compliance](#) or [certificate of conformity](#). Details required to be identified on the Certificate of Conformance (CoC) can be very extensive, but as a minimum may include:

- contract / purchase order number (unique identifier)
- compliance to referenced specification (BS EN 10204 certificate)
- drawing number (if appropriate)
- item identification and number of items covered under CoC
- applicable signatory

Management Review

Upon request, the Contractor should provide the Customer with copies of management review records relevant to the contract work scope.

The Contractor should notify the Customer of any management review actions which will affect compliance with contractual requirements.

Management review output should identify responsible persons and due dates for completion of agreed action.

Release of Goods

Product identified as requiring an interim release note should only be dispatched by the Contractor when authorisation has been obtained from the Customer by the issue of appropriate written certification.

The Contractor should only dispatch to the Customer, any product for which authorisation has been obtained from the Customer by the issue of signed permission / approval.

Lifetime Records defined in the contract as being required by the Customer should be accepted as defined and its sub-sets, with a name, signature and date on the front sheet of the LTR pack by both the Contractor and the Customer prior to product release.

Release of Goods on Nuclear Sites

Inspection checklists and associated Contractor's Manufacture, Inspection and Test Plans may be utilised to control the release of goods manufactured on site.

Records

The Contractor should ensure that all Lifetime Records (LTRs) are compiled in accordance with the Customer's requirements concurrently with the activity to which they relate. This also applies to LTRs generated by Sub-Contractors, One set of the LTRs after acceptance by the Customer should be in the contract documents delivered to the Customer, unless stated otherwise.

Where radiography is required, the Contractor should conform to the mandated General Procedures and Guidance specification for radiographic examination.

Delivery and Receipt

Preservation of Product

Contractors are expected to inform the Customer of specific requirements and processes that are necessary for the ongoing maintenance and preservation of product(s) before and during use. Operations and maintenance manuals may form part of the deliverables.

The Contractor should ensure the security of product and its constituent parts during internal processing and delivery to the Customer.

On nuclear site contracts the Customer may request the Contractor to deliver to a specified storage area at the Nuclear Licensed site, and which will be provided by the Site Licensee. The storage area must satisfy the relevant requirements of the associated Site Licence company specifications and must be maintained to agreed standards. The specified storage area must contain a secure quarantine area.

The Contractor should maintain an appropriate plant and materials schedule containing the following as a minimum for each item of plant and material:

- Quality Grading;
- safety function class;
- relevant specifications;
- Contractor and location;
- resource requirements;
- Manufacture, Inspection and Test Plan requirements;
- factory acceptance test requirements;
- functional test requirements;
- certification requirements;
- release requirements;
- anticipated delivery dates

On nuclear sites the Contractor should have a Foreign Materials Exclusion (FME) process. The process should include but is not limited to the following:

- identification as to whether Foreign Materials Exclusion principles apply to the scope of work and if so, when, i.e. final vessel closures, works testing, dismantling, packing and dispatch;
- identification, segregation and management of Foreign Materials Exclusion areas;
- identification and use of materials, equipment, processes and systems demonstrating their status, i.e. 5S, shadow boards, lanyards, work management, materials control including items to be removed or added such as bolts, washers, items in or items out, and management of waste arising such as swarf;
- training and awareness information including good housekeeping for personnel involved in such activities.

Appendix A – Related references

The following reference documents may provide further information on Nuclear Safety and also identifies standards that may be included in contracts by individual Nuclear Licensees:

- ASME National Quality Assurance (NQA1) Certification
- Babcock – SBU(D)-SD-129: Design and Quality Assurance Standards for Structures Systems & Components
- BAE Systems Submarines – Standard Submarine Quality Assurance Clauses (SSQAC)
- BS EN 10204:2004 – Metallic products - Types of inspection documents
- EDF / NNB – GQAS (Quality Assurance for Contracts)
- EN ISO 9001: Quality Management System Requirements
- Horizon – GQR: General Quality Requirements
- Institute of Nuclear Power Operators (INPO)
- International Atomic Energy Agency - Safety Standards
 - GS-R-3: The Management System for Facilities and Activities
 - GS-G-3.1: Application of the Management System for Facilities and Activities
 - GS-G-3.5: The Management System for Nuclear Installations
 - Fundamental Safety Principles, No. SF-1
- Magnox – MCP-004: The Graded Application of Quality Assurance
- MOD Defence Standards
 - Def Stan 02-884: Submarine Enterprise Standard Quality Requirements
 - Def Stan 05-135: Avoidance of Counterfeit Materiel
 - Def Stan 02-207: Quality Management Framework and Requirements for Materiel Safety in Submarines
- NATO – Allied Quality Assurance Publications
 - AQAP 2105: Requirements for Deliverable Quality Plans
 - AQAP 2110: QA Requirements for Design, Development and Production
 - AQAP 2210: Supplementary Software Quality assurance requirements
- NQSA – NSQ 100: Nuclear Safety and Quality Management System - Requirements
- ONR – Technical Assessment guides
 - TAG 33: Licensee Management of Records
 - TAG 49: Licensee use of Contractors and Intelligent Customer capability
 - TAG 77: Supply Chain Management Arrangements for the Procurement of Nuclear Safety Related Items or Services
- “Operating Experience and Learning” A Guide to Good Practice, produced by the OE and Learning Group and published on behalf of the Nuclear Industry Safety Directors Forum, First Editon, April 2015
- Rolls Royce - SABRe, GS3001: Nuclear Submarines – General QA Requirements
- Sellafield – SLM 4.06.02: Contract Quality Requirements Manual
- SSP 25: Quality Assurance for Safety in Submarines

Appendix B – Typical Oversight & Assurance Activities

	Activities for Oversight of Quality Assurance
Pre-Contract	'Opening-up' meetings to review tender submission
	Assessment of Contractor's resources and capability (award stage)
	Advising on Contractor's arrangements for oversight and assurance
	Advising on Contractor selection
Contract Placement	Contract 'opening-up' meetings
	Ensure the understanding of Customer / contract-requirements, oversight and assurance arrangements
	Review and approval / acceptance of quality documentation
	Review and approval / acceptance of Quality Plan
	Review and approval / acceptance of Manufacturing Inspection and Test Plan (MITP)
	Advising on quality and technical matters
	Advising on manufacturing process / 'constructability'
Design	Advising on sub-supplier selection
	Understanding of Customer requirements and design inputs / outputs
	Review of documentation and design inputs / outputs
Product and Service Realisation	Ongoing review, validation and verification of design and development control processes
	Defining and managing Quality roles and responsibilities (SQEP) across the contract
	Contract 'opening-up' meetings
	Review that works information has cascaded through the Supply Chain
	Designated Quality Interface between Customer and Contractor
	Specialist advice or input to resolve manufacturing and delivery issues
	Systems to capture Deviation / NCR / TQ / PP / Concession data
	Processes to input Deviation / NCR / TQ / PP / Concession data
	Ongoing assessment of Contractor performance
	Assurance the products and services meet the requirements of the Customer / contract
	Ongoing approval of Contractor's SQEP resource
	Manufacturing Inspection and Test Plan (MITP) activities
	Review and approval of inspection and test reports (and trend)
	Compiling and collating Lifetime Records (LTR)
Verification of measuring and test equipment	
Acceptance and Release	Inspection reports
	Final inspection of products and services
	Review and approval of interim Lifetime Records
	Certification of Quality Plan completion
	Certificates of release acceptance
Delivery and Receipt	Final review and approval of Lifetime Records
	Receipt inspection
	Contractor Performance Report Questionnaire

Appendix C – Glossary

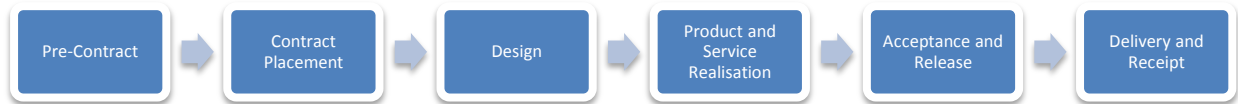
Definition	Description
Audit	Systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled
Assessment	Process for analysing a Contractor's competencies, facilities and equipment to ensure that they have amongst other things the capability to conform to the Contract requirements, delivering products and services safely, to schedule, of the correct quality and to cost
Assurance	A systematic approach to confirm activities are being completed as per the requirements, to the appropriate standard and to confirm that arrangements comply with required legislation, standards and customer requirements
Capability	The sum of knowledge, expertise and capacity of an organisation to achieve its goals
Change Control	Change control is a systematic approach to managing all changes made to a product or system. The purpose is to ensure that no unnecessary changes are made, that all changes are documented, that services are not unnecessarily disrupted and that resources are used efficiently
Concessions	Permission to use or release of product or service that does not conform to requirements
Contract	Binding agreement between the Customer and a Contractor
Contractor/Sub-Contractor	Supplier or individual who provides products or services in accordance with the Customer's Contract requirements. Contractor is an all-inclusive term which may be used in place of: supplier, Contractor, Sub-Contractor or consultant
Counterfeit	Items intentionally manufactured or altered to imitate a legitimate product in order to pass themselves off as genuine.
CFSI	Counterfeit, Fraudulent and Suspect Items: also includes services
Customer	The organisation receiving the Product or Service. May be defined as the Nuclear Licensee or the next tier up in the Supply Chain from the Contractor in question
Deviation	Departures from the originally specified requirements of a product prior to realisation. Deviations can emerge at any stage of the Supply Chain, including design, manufacturing, storage and transportation.
Flow-down	Distribution of the Customer's Contract requirements as applicable to the specified Quality Grade to every tier of the Supply Chain where the risk associated with the procurement of product or services continues to be a Quality grade 01, 02 or 03
Foreign material Exclusion (FME)	The process of preventing the introduction of outside debris into an area or areas where that debris poses an economic risk or safety hazard
Fraudulent	Fraudulent items are misrepresented with intent to deceive, including items with incorrect identification or false certifications.
Hold Point	Hold Point is a mandatory verification point beyond which a work cannot proceed without approval by the Engineer / Inspector. The work cannot proceed until the Engineer / Inspector is able to verify the quality of the completed work and releases the Hold by means of Inspection Request approval.
Inspector	The independent body or organisation that verifies that items or services have been designed, constructed and tested in accordance with the technical Specification. The inspection authority should have suitable competencies.
Intelligent Customer	The capability of an organisation to understand where and when work is needed; specify what needs to be done; understand and set suitable standards; supervise and control the work; and review, evaluate and accept the work carried out on its behalf.
Learning from Experience (LfE)	See also Operational Experience (OE)
Lifetime Records (LTR)	Record(s) that provide documentary evidence of the research & development, design, build, construction, commissioning, decommissioning and demolition of/on a nuclear installation

Manufacturer/Contractor/Vendor	The supplier organisation that designs, constructs and tests items or services in accordance with a Customer's purchase order. This term includes the main manufacturer and any sub-contractors in the Supply Chain. It also encompasses the scenario where design, manufacture, and installation might be carried out by different organisations.
Manufacture, Inspection and Test Plan (MITP)	Document which defines the sequential Quality Control, testing activities and associated arrangements that are applied to a specific scope of work or individual piece of plant or equipment
Non-conforming or NCR (Non-conforming Report)	Non-fulfillment of a requirement. Non-conformances can emerge at any stage of the Supply Chain, including design, manufacturing, storage and transportation.
Nuclear Licensee	The body corporate that has been granted a Nuclear Site Licence under the Nuclear Installations Act 1965 (as amended), which permits it to carry out a defined scope of activities on a delineated site (NIA).
Nuclear Safety	The protection of workers, the public and the environment from undue radiation hazards by achievement of proper operating conditions, prevention of accident and the mitigation of accident consequences,. In this document safety means nuclear safety unless otherwise stated.
Operational Experience (OE)	The organisation systematically and effectively collects, evaluates, and implements lessons from relevant internal and external operating experience information in a timely manner
Product	TBC - to include components, equipment (incl. free-issue / customer-issued), software, maintenance, decommissioning etc
Production Permit or PP	Written authorisation from the Licensee, prior to production, to deviate from specified requirements
Quality Grade	A graded approach to the procurement and supply of products and services as outlined within Section 6 of this guide
Quality Management System	A management system to direct a unit and control an organisation with regard to quality; a combination of resources and means with which quality is realised.
Quality Plan	A document or set of documents setting out the specific quality practices, resources and sequence of activities relevant to realisation of a particular item or service. A quality plan is useful for formalising and co-ordinating the interactions of various organisations, through the identification of witness and hold points.
Root Cause Analysis	Root cause analysis (RCA) is a method of problem solving used for identifying the root causes of faults or problems
Safety Culture	The assembly of characteristics and attitudes in organisations and individuals which establishes that, as an overriding priority, protection and safety issues receive the attention warranted by their significance.
Supply Chain	The network of organisations that are involved in the different processes and activities that contribute to the provision of products or services to the purchaser.
Suspect Item	Indication by inspection, testing or documentation that the Product may not conform to specified standards, specifications and/or technical requirements. Additional information or investigation is needed to determine whether the suspect item is acceptable, Non-conforming, Counterfeit or Fraudulent.
Technical Query or TQ	Request for clarification of technical or engineering information typically contained in drawings, specifications and contract documents. The response should provide clarification but must not in its own right change design intent.
Technical Specification	The Technical Specification defines the system, components and items, as applicable, in sufficient detail to provide a complete basis for the design, manufacture, testing and installation.

Appendix D – Quality Management – Performance metrics

This appendix outlines example metrics which Contractors may be asked to report against by their Customers in order to measure performance around Quality management. Contractors may also wish to use these metrics with their suppliers.

Metrics will be listed against the following value chain Map in-order to clarify which aspects of contractor performance are being measured:



General Principles

The Contractor should in accordance with the Contract requirements establish and agree a set of performance metrics. The metrics may include as a minimum the measurement of the Contractor’s quality, safety, schedule, and cost performance. Key Performance Indicators such as Customer Service, Relationship/Integration, Innovation, contract adherence, Right-First-Time (RFT) or On Time In Full (OTIF) may also be measured.

The Contractor should report the agreed cumulative performance metrics to the Customer at an agreed frequency. The Contractor should also report Sub-contractor performance to the Customer.

The Contractor should measure the performance of their Sub-contractors in line with the Customer Contract. Upon request, the performance data should be shared with the Customer for the purpose of measurement of Supply Chain performance.

The Contractor should ensure specific, measurable, achievable, realistic and time bound (SMART) action is taken if Sub-contractor performance is not achieving the required standard or upon the identification of a deteriorating and/or adverse trends.

Over-arching metrics

There are a number of metrics which are not applicable to just one specific part of the value chain. These are described below as “Over-arching metrics”. Sub headings have been used to describe the activities which these metrics monitor:

Assurance

- Self-assessments / independent assessments completed outside of the normal quality assurance process.
- Recorded and reported quality related events data is collated using condition reports, NCR, quality performance reporting etc.

Ongoing Audit results

- continual performance monitoring during and post-delivery of a contract.
- Root Cause Analysis
- adherence to, completion and accuracy of Quality Assurance requisites.

Organisational and individual learning

- metrics capturing proactive approach to delivering a contract for example: pre job briefs, Operational experience (OE), peer to peer coaching, tool box talks, coaching and benchmarking.

- quality events and lessons learnt
- performance against action plans or improvement programmes

Health, Safety and Environmental Requirements

- Metrics capturing proactive approach to delivering a contract safely including:-
 - Nuclear Safety Culture – awareness and understanding of.
 - HSE managed appropriately and compliantly with plan, statements, rules and practices;
 - good housekeeping in the work area established and maintained;
 - there were any Lost Time Accidents, near misses or loss of control forms recorded against the contract;
 - the correct HSE documentation submitted with the product (COSHH, REACH etc.)

Pre-Contract

- Contractor compliant with Customer pre-contract requirements which may include, but not limited to, pre-contract audit/assessment, contractor approval criteria, or Customer defined contractor qualification requisites.
- Quality Management System audit action, progress and completion.

Contract Placement

- Customer contract quality requirements understood and implemented. Metrics may also be implemented on the flow down of those contract quality requirements throughout the tiers of the Supply Chain.
- Performance may also be measured on the completion of contract inaugural activities.
- Procurement / programme management process compliance to customer requirements e.g. on-time delivery of agreed and identified milestones

Design (if applicable)

- Technical Specification compliance
- Number of changes to a contract during the contract life cycle
- Change management process adherence

Product and Service realisation

Typical measures / metrics for product and service quality achieved during the delivery of a Contract:

Documents		Number Submitted	Number Reviewed	Number Accepted	Percentage RFT	Number of Revisions
	Quality Plans					
	Inspection and Test Plans					
	Weld Procedures					
	NDE Procedures					
	Life-Time Records					
Inspection Activities		Number Notified	Number Completed	Number Accepted	Percentage RFT	
	Weld set up					
	Visual					

	NDE				
	Factory Acceptance Testing				
Deviations / NCRs		Number Submitted	Number Reviewed	Number Accepted	Percentage RFT
	Technical Queries				
	Concessions				
	Product Permits				

Acceptance and Release

- Adherence to schedule
- Completeness to contract requirements
- Notification accuracy
- Availability of supporting material to enable the release of the product or service
- Lines Accepted – no. of items accepted
- “On Receipt” describes non-conformances identified prior to landing and acceptance of the goods/service.
- Supporting documentation – e.g. declarations of conformity, test results

Delivery and Receipt

Delivery performance - Metrics established to detail the performance in delivering the contract for example compliance with the contract requirements including: on time delivery, product quality, service quality, commercial performance, planning, commissioning and quantity required.

- Lines delivered / (RFT)
- “Latent Defect” describes non-conformances identified following acceptance and issue.
- Documentation
 - % of RFT documents submitted and approved/accepted i.e. Quality plans, Welding Procedures, NDE Procedures etc.
 - Review and Approval of contractor records for final submission as Lifetime Records

List of SDF Publications

Codes of Practice

SDF Sub-group Good Practice Guide to Supply Chain Quality Requirements.

Good Practice Guides

SDF Sub-group Good Practice Guide to Supply Chain Quality Requirements.

Other Guidance

Key Attributes of an Excellent Nuclear Security Culture

Right First Time Supply Chains: How to Write a Usable Supply Chain